IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
McCormick et al.	:	Patent Art Unit: TBA
Division of Serial No. 09/522,900	:	Examiner: TBA
Filed: 8 February 2002	:	
For: Self Antigen Vaccines for Treating B Cell Lymphomas and Other Cancers	:	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to prosecution on the merits, kindly amend the application as follows:

IN THE SPECIFICATION

Kindly amend the specification as follows:

Page 10, line 9, before "though" insert --SEQ ID NO:59--.

Page 29, line 22, following "cg" insert – SEQ ID NO:60--.

Page 37, line 11, following " '5" insert – SEQ ID NO:61--; and

line 23, following " '5" insert – SEQ ID NO:62--.

IN THE CLAIMS:

Kindly cancel claims 1-40 and 51-53, without prejudice.

Kindly amend the claims as follows:

41. A method of inducing a tumor-specific immune antibody response in (i) a tumor-bearing subject or (ii) a subject who had a tumor and was treated so that no tumor is clinically or radiographically evident, comprising administering to said subject an effective amount of a vaccine composition comprising:

(A) a polypeptide self-antigen useful as a tumor-specific vaccine in a subject with a tumor or at risk of developing a tumor, encoded at least in part by a nucleic acid in the cells of said tumor, which polypeptide:

(a) includes an epitope or epitopes unique to, or overexpressed by, cells of said tumor, thereby distinguishing said tumor from all other tumors (i) of the same or different histological type, (ii) in said subject or in another member of said subject's species;

(b) is produced in a cell or organism that has been transformed or transfected with said nucleic acid derived from said tumor of said subject;

(c) is obtainable from said cell or organism in correctly folded form, without a need for denaturation and renaturation and mimics said epitope or epitopes in their native form; and

(d) is capable of inducing an immune response in a mammal, including said subject, without a need for adjuvant or other immunostimulatory materials, so that administration of said polypeptide results in an antibody or cell-mediated immune response to said epitope or epitopes; and

(B) a pharmaceutically acceptable carrier or excipient.

42. The method of claim 41, wherein said polypeptide is a single chain antibody.

43. The method of claim 41 wherein the tumor is a B-cell lymphoma.

44. The method of claim 41, wherein the polypeptide is an scFv that includes at least part of the V_H and the V_L domains.

Kindly add the following new claims.

--54. The method of claim 44 wherein said domains are linked by an amino acid linker that:

(a) has between one and about 50 residues;

(b) consists of between one and 12 different amino acids, and

(c) facilitates secretion and correct folding of said polypeptide to mimic the tumor epitope in its native form in or on said tumor cell.

55. The method of claim 54 wherein the linker is a member of a randomized library of linkers that vary in size and sequence, and said library is encoded by nucleic acid sequences consisting of a repeated pattern of degenerate repeated triplet nucleotides having the following requirements:

(i) position 1 of each repeated triplet cannot be the same nucleotide as position 2 of the repeated triplet;

(ii) position 2 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet; or

(iii) position 1 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet.

56. The method of claim 55, wherein the nucleotide in the first and second positions of each repeated triplet is selected from any two of deoxyadenosine, deoxyguanosine, deoxycytidine or deoxythymidine.

57. The method of claim 56, wherein

(i) position 1 of each repeated triplet is deoxyadenosine or deoxyguanosine;

(ii) position 2 of each repeated triplet is deoxycytidine or deoxyguanosine; and

(iii) position 3 of each repeated triplet is deoxythymidine.--

REMARKS

The Examiner hereby is authorized to obtain the CRF of the Sequence Listing from the parent application for use herein. The content of the CRF is the same as the paper copy attached hereto, which also is the same as the paper copy filed in the parent application.

Favorable consideration and early indication of allowance are solicited earnestly.

Respectfully submitted,

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41. A method of inducing a tumor-specific immune antibody response in (i) a tumor-bearing subject or (ii) a subject who had a tumor and was treated so that no tumor is clinically or radiographically evident, comprising administering to said subject an effective amount of [the] a vaccine composition [of claims 29] comprising:

(A) a polypeptide self-antigen useful as a tumor-specific vaccine in a subject with a tumor or at risk of developing a tumor, encoded at least in part by a nucleic acid in the cells of said tumor, which polypeptide:

(a) includes an epitope or epitopes unique to, or overexpressed by, cells of said tumor, thereby distinguishing said tumor from all other tumors (i) of the same or different histological type, (ii) in said subject or in another member of said subject's species;

(b) is produced in a cell or organism that has been transformed or transfected with said nucleic acid derived from said tumor of said subject;

(c) is obtainable from said cell or organism in correctly folded form, without a need for denaturation and renaturation and mimics said epitope or epitopes in their native form; and

(d) is capable of inducing an immune response in a mammal, including said subject, without a need for adjuvant or other immunostimulatory materials, so that administration of said polypeptide results in an antibody or cell-mediated immune response to said epitope or epitopes; and

(B). a pharmaceutically acceptable carrier or excipient.

42. [A] The method of [inducing a tumor-specific immune antibody response in (i) a tumor-bearing subject or (ii) a subject who had a tumor and was treated so that no tumor is clinically or radiographically evident, comprising administering to said subject an effective amount of the vaccine composition of claims 33] claim 41, wherein said polypeptide is a single chain antibody.

43. The method of claim 41 wherein the tumor [Is] is a B-cell lymphoma.

44. The method of claim [43] 41, wherein the polypeptide is [the] an scFv that includes at least part of the V_H and the V_L domains.